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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Keith D. ALLEN et al.

Serial No.: 10/010,065

Filed: December 5, 2001

**Title: Transgenic Mice Containing Glucagon
Receptor Gene Disruptions**

Group Art Unit: 1632

Examiner: Bertoglio, Valerie

Customer No. 26619

Docket/Order No. R-648

Date: November 25, 2002

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Office Action mailed October 24, 2002, concerning the Examiner's restriction to the claims, Applicants hereby provisionally elect, with traverse, Invention III (claims 9 and 18-33), drawn to a transgenic animal comprising a disruption in a glucagon receptor gene.

In the restriction, the Examiner asserts that claims 1-56 are drawn to twelve distinct subjects, grouped as: Invention I (claims 1-4), drawn to a nucleic acid construct and methods of making the construct; Invention II (claims 5-7, 10 and 34), drawn to cells with a disruption in a glucagon receptor gene; Invention III (claims 9 and 18-33), drawn to a transgenic animal comprising a disruption in a glucagon receptor gene; Invention IV (claims 12, 13, 36 and 37), drawn to methods of using a transgenic animal comprising a disruption in a glucagon receptor gene to test agents; Invention V (claims 11 and 35), drawn to a method of making a transgenic animal; Invention VI (claims 14-16, 38 and 39), drawn to methods of using cells with a disruption in a glucagon receptor gene to test agents; Invention VII (claims 17, 40 and 41), drawn to an agent; Invention VIII (claims 43 and 54), drawn to a method of treating obesity; Invention IX (claims 43 and 55), drawn to a method of treating a diabetic condition; Invention X (claims 44-47, 49, 50, 52 and 53), drawn to a method of identifying an agent that inhibits the activity or function of a glucagon receptor by contacting the agent to a cell that expresses the glucagon receptor gene, and the agent; Invention XI (claims 48 and 51), drawn to a method of identifying an agent that has an effect on obesity using a mouse expressing a glucagon receptor gene; and Invention XII (claim 56), drawn to a database.

Applicants respectfully request reconsideration and withdrawal of the requirement. In particular, Applicants request reconsideration of the requirement for restriction between Inventions I, II and III. Applicants do not traverse the requirement for restriction between Inventions IV through XII each from the other and each from Inventions I, II and III.

The Examiner asserts that the claims of Invention I and Invention II are patentably distinct in that the nucleic acid construct of Invention I can be used as a probe while the cells of Invention II can be used in *in vitro* assays of glucagon receptor function. The Applicants disagree with the Examiner's conclusion. Applicants submit that a reasonable search or examination of the prior art would produce results related to the subject matter of both invention groups, and would not put serious burden on the Examiner.

The Examiner also asserts that the claims of Invention I and Invention III are patentably distinct in that the nucleic acid construct of Invention I can be used as a probe, while the transgenic animal of Invention III can be used in *in vivo* assays to determine agents that modulate glucagon receptor expression. The Applicants disagree with the Examiner's conclusion. Any search or examination of the prior art conducted on one of these aspects, *e.g.* glucagon receptor deficient transgenic animals, would produce results that would encompass the transgenic animals and the nucleic acid construct. Thus, the additional burden of a separate search or examination would not be required.

It is also asserted by the Examiner that the claims of Invention II and Invention III are patentably distinct because the cells of Invention II can be used in *in vitro* assays to determine differential gene expression while the transgenic animals of Invention III can be used in *in vivo* assays to determine agents that modulate glucagon receptor expression. The Applicants disagree with the Examiner's conclusion. The Applicants believe that a reasonable search of the prior art would produce results related to both cells and animals comprising glucagon receptor disruptions, and the use of such cells and animals. A search and examination of the claims of each of these inventions, therefore, can be made without additional burden on the Examiner.

As stated in MPEP §803, the requirements for a proper claim restriction are as follows: "(a) the inventions must be independent or distinct as claimed; and (b) there must be a serious burden on the examiner if restriction is required."

A proper claim restriction must place a "serious burden" on the Examiner if the claims were examined without a restriction. In order to establish a serious burden, the Examiner must "show by appropriate explanation one of the following: separate classification thereof, a separate status in the

art, or a different field of search.” This showing of a serious burden is required even though the claimed inventions have been shown to be distinct. See MPEP §808.02

The instant Office Action asserts that restriction is warranted between Inventions I and II, I and III and II and III in that the claimed inventions can be used for different functions. The Applicants submit that separate uses for the claimed inventions is not sufficient to establish a serious burden if the inventions were searched together. The Applicants do not believe that the Examiner has fulfilled the requirements for a proper claim restriction based on a serious burden as stated in the MPEP. The Applicants believe that a search of any one of Invention groups I, II or III would produce results that would encompass the subject matter of each of the three invention groups. Thus, a serious burden would not be placed on the Examiner in order to conduct a search and examination of the claims of Inventions I, II and III.

Although the Applicants have provisionally elected Invention III for the purposes of advancing prosecution of the present application, Applicants contend for the foregoing reasons that the restriction requirement between Invention I, Invention II and Invention III is improper. Accordingly, Applicants respectfully request reconsideration and withdrawal of the requirement.

Respectfully submitted,

Date: 11/25/02

Kelly L. Quast
Kelly L. Quast (Reg. No. 52,141)

Deltagen, Inc.
740 Bay Road
Redwood City, CA 94063
(650) 569-5100

CERTIFICATE OF MAILING UNDER 37 CFR 1.8

I hereby certify that this correspondence and its listed enclosures is being deposited with the United States Postal Service as First Class Mail, postage paid, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on **November 25, 2002**

Name: **Deborah A. Mojarro**

Signed: Deborah A. Mojarro

Date: 11/25/02